DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 2, 2014

Shanghai GaoHui Rubber and Plastic Company
c/o Ms. Rhonda Thompson Alexander
Registrar Corp.
144 Research Drive
Hampton, VA 23666

Re: K140874
Trade/Device Name: GH Disposable and GH Reusable Blood Pressure Cuffs
Regulation Number: 21 CFR 870.1120
Regulatory Class: Class II
Product Code: DXQ
Dated: July 23, 2014
Received: July 24, 2014

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

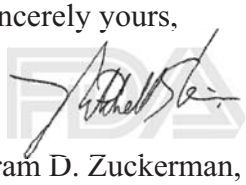
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140874

Device Name
GH Reusable Blood Pressure Cuff

Indications for Use *(Describe)*
The GH blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in neonatal, pediatric and adult sizes. The cuff is not designed, sold or intended for use except as indicated.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140874

Device Name
GH Disposable Blood Pressure Cuff

Indications for Use *(Describe)*
The GH Disposable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single patient use. It is available in neonatal, pediatric and adult sizes. The cuff is not designed, sold or intended for use except as indicated.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY (21 CFR 807.92)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92

The assigned 510(k) number is: K140874

Premarket Notification [510(k)] Summary

A. General Information

Submitter's Name:	Shanghai GaoHui Rubber and Plastic Company
Address:	No 381, Hong An Road, Xinnong Zhujing Zhen Jinshan District, China 201503
Telephone:	+86 21 54360656
Fax Number:	+86 21 54357084
Contact Person:	Richard Gao, Vice General Manager
Date Prepared:	February 12, 2014

B. Device

Trade Name:	GH Disposable Blood Pressure Cuff GH Reusable Blood Pressure Cuff
Common Name:	Blood Pressure Cuff
Product Code:	DXQ
Class:	Class 2
Regulation Number:	21 CFR 870.1120

C. Identification of Legally Marketed Predicate Device

Name:	Non-Invasive Blood Pressure Cuff
Manufacture:	Caremate Medical Device Co., Ltd.
K Number:	K102792
Name:	Non-Invasive Blood Pressure Cuff
Manufacture:	Unimed Medical Supplies Inc.
K Number:	K112544

D. Description of the Device

Both devices comprise tubing attached to an inelastic sleeve with an integrated inflatable bladder that is wrapped around the patient's limb, secured by hook and loop closure, and used to measure the patient's blood pressure. The device tubing is connected to a non-invasive blood pressure measurement system.

E. Intended Use

The GH disposable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for

single-patient use. It is available in neonatal, pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.

The GH reusable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in neonatal, pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.

F. Comparison to the Predicate Device

Features	**Shanghai GaoHui Rubber and Plastic Company** *GH Disposable Blood Pressure Cuff*	**Caremate Medical Device Co., Ltd.** *Non-invasive Blood Pressure Cuff*
Intended use	The GH disposable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in neonatal, pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.	Indirect measurement of blood pressure
Patient Populations	Adults/Pediatrics	Adults/Pediatrics
Tube Configuration	One or two tube	One or two tube
Size (range in cm)	Conform to AHA bladder sizes	Conform to AHA bladder sizes
	recommendations	recommendations
	Neonate 1 (3-6)	Neonate 1 (3.3-5.6)
	Neonate 2 (4-7)	Neonate 2 (4.2-7.1)
	Neonate 3 (5-11)	Neonate 3 (5-10.5)
	Neonate 4 (7-12)	Neonate 4 (6.9-11.7)
	Neonate 5 (9-15)	Neonate 5 (8.9-15)
	Neonate 6 (8-12)	Neonate 6 (7.7-10.5)
	Neonate 7 (10-14)	Neonate 7 (9.8-13.3)
	Neonate 8 (12-17)	Neonate 8 (12.4-16.8)
	Infant 9(16-22)	Infant 9(15.8-21.3)
	Child 10(20-27)	Child 10(20-27)
	Small adult 11(26-35)	Small adult 11(25.3-34.3)
	Adult 12 (32-43)	Adult 12 (32.1-43.4)
	Thigh 13 (46-66)	Thigh 13 (46-66)
Sterility	Not supplied sterile	Not supplied sterile
Pressure limits	O-300mmHg	0-300mmHg
Sterility	Non-sterile	Non-sterile

Biocompatibility	Comply with ISO **10993** biocompatibility evaluation	Comply with ISO **10993** biocompatibility evaluation

The GH Disposable Blood Pressure Cuff has the same Intended Use, basic construction, and technology specification as the predicated device. Both devices are wrapped the patient's arm or leg and secured by a hook and loop fastener commonly called Velcro. Both devices are available in the same size and range and are intended for the same patient populations. The materials of both devices are all conformed to ISO 10993. We extend the length of the cuffs in order to accommodate special groups, such as overweight subjects. Based on the performance testing in this submission, the slight difference on the range of these blood pressure cuffs does not raise any safety or effectiveness issue.

Features	**Shanghai GaoHui Rubber and Plastic Company** *GH Reusable Blood Pressure Cuff*	**Unimed Medical Supplies Inc.** **K112544** *Non-invasive Blood Pressure -Cuff*
Intended Use	Indirect measurement of blood pressure	Indirect measurement of blood pressure
Indications for use	The GH Reusable Blood Pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in neonatal, pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.	The Unimed Blood Pressure Cuff is an accessory used in conjunction with non-invasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in pediatric and adult sizes. The cuff is not designed, sold or intended for use except as indicated.
Patient Populations	Adults/Pediatrics	Adults/Pediatrics
Tube Configuration	One or two tube	One or two tube
Size (range in cm)	Conform to AHA bladder sizes	Conform to AHA bladder sizes
	recommendations	recommendations
	Neonate 1 (3-6)	Neonatal (6-11) Infant (10-19) Pediatric(16-26) Small adult(20-28) Adult (25-35) Large Adult (33-47) Thigh (46-66)
	Neonate 2 (4-7)	
	Neonate 3 (5-11)	
	Neonate 4 (7-12)	
	Neonate 5 (9-15)	
	Neonate 6 (8-12)	
	Neonate 7 (10-14)	
	Neonate 8 (12-17)	
	Infant 9(16-22)	
	Child 10(20-27)	
	Small adult 11(26-35)	
	Adult 12 (32-43)	
	Thigh 13 (46-66)	

Repeated inflation	10,000 inflations 3,000 hook and loop closures	10,000 inflations 3,000 hook and loop closures
Pressure limits	0-300mmHg	0-300mmHg
Sterility	Non-sterile	Non-sterile
Biocompatibility	Comply with ISO **10993** biocompatibility evaluation	Comply with ISO **10993** biocompatibility evaluation
Material of cuff	Cuff : woven nylon. light and soft, Nontoxic, anti bacterial	Cuff: Pu Synthetic Leather light and soft, Nontoxic, anti bacterial
Material of tube	PVC : stable ; corrosion resistance ; heat-resistance	PVC : stable ; corrosion resistance ; heat-resistance
Material of Bladder	TPU : stable ; corrosion resistance ;	TPU : stable ; corrosion resistance ;
Material of hook&loop fastener	Nylon: stable,corrosion resistance ; heat-resistance , anti pollution,fast colors	Nylon:stable,corrosion resistance ; heat-resistance , anti pollution,fast colors

G. Summary of Testing

Both new devices were designed and manufactured in accordance with the following standards:

- ANSI/AAMI SPlO, Manual, electronic or automated sphygmomanometers, 2002+AI.:2003+A2:2006+(R)2008
- ISO 10993-1, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process, 2009
- ISO 10993-5, Biological evaluation of medical devices- PartS5: Tests for In Vitro cytotoxicity, 2009
- ISO 10993-10, Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity, 2002+A1 :2006

H. Conclusion of Substantial Equivalence

Based on the comparison of intended use, design, materials and performance, we conclude that the new devices are substantially equivalent to the predicates. The differences between the devices do not raise new questions of safety and effectiveness.